California Law Update

By Robert M. Bodzin December 2004

Federal Preemption Prohibits California From Imposing Additional Proposition 65 Labeling Requirements On Pharmaceuticals In Certain Circumstances

INTRODUCTION

The California Supreme Court recently defined the limits by which different labeling could exist in certain circumstances on pharmaceuticals products sold inside and outside the State. The case, Dowhal v. SmithKline Beecham Consumer Healthcare, 32 Cal. 4th 910 (2004) held that the Food and Drug Administration (the FDA) was entitled to reject California's "Proposition 65" labeling when the latter directly conflicted with both the wording and the intent of the Federal counterpart.

BACKGROUND OF UNDERLYING CASE

The nature of the dispute lies in the fact the California is the only State permitted to offer labeling and warning labels that are not identical to those established by the FDA. This exception was created when the FDA Modernization Act of 1997 specifically allowed Proposition 65 labeling to remain in the effect and not be precluded by federal uniform standards. The Court of Appeal originally interpreted the "savings clause" of the FDA Modernization Act as a blanket provision that allowed any Proposition 65 labeling to exist, even if it conflicted with the Federal labeling[1].

At issue were products designed to help people stop smoking. Since these patch and gum products contain nicotine, Plaintiff, acting on behalf of the People of the State of California, requested a label consistent with Proposition 65, that stated this product can cause reproductive harm in infants and the product could cause an increase in an infant's heart rate.

The FDA rejected this label and instead, posted warning that stated as follows:

> If you are pregnant or breast feeding, only use this medication on the advice of your healthcare provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risk to your child from this medicine are not fully known.

The FDA rejected Mr. Dowhal's proposed label because it was mislead in that it highlighted the risk that an infant's heart rate could increase and potentially cause a false sense of security that no other side effects could occur. Further, the FDA rejected the label because it could discourage pregnant women from trying the produce and instead to keep smoking. The California Court of Appeal blocked the FDA's efforts to prevent Mr. Dowhal's labeling from being adopted and it held that the savings clause of the FDA Modernization Act explicitly permitted different labeling to exist.

THE CALIFORNIA SUPREME COURT DECISION

In reviewing the Court of Appeal's decision, the Supreme Court reviewed the extent to which Proposition 65 was not preempted by Federal law and the balancing test applied in a preemption analysis. The Supreme Court explained that Federal preemption arises from three circumstances which are as follows: (1) Explicit preemption; (2) preemption based on the fact that Congress set a pervasive regulatory scheme that clearly and manifestly occupies the field of regulation in this area; (3) conflict preemption. The Supreme Court held that the first two types of preemption were inapplicable and that in this instance, conflict preemption applied because the FDA had the right to prohibit California from imposing labeling requirements that directly conflicts with the Federal government's goal of discouraging and eliminating smoking in pregnant women. In rejecting Mr. Dowhal's warning label, the Supreme Court also referenced one of the leading cases in California on product labeling which is Carlin v. Superior Court, 13 Cal. 4th 1104 (1996). Carlin held that pharmaceutical companies could be liable if they issued a truthful warning, if that labeling was misleading or failed to communicate the facts necessary for the protection of the users.

In this instance, the Supreme Court held that Mr. Dowhal's proposed warning was misleading and that it could act to prevent pregnant women from trying to stop smoking. In that regard, the Proposition 65 label directly conflicted with the Federal Government's goals.

SIGNIFICANCE OF DECISION

Manufacturers of pharmaceuticals should be cognizant that product labels and warnings may be required to carry information in California that is different than those sold elsewhere. Although the California Supreme Court struck down the label proposed by Mr. Dowhal, it did not create a "bright line" rule whereby any different labeling in California is rejected. The Supreme Court's decision leaves open the possibility that different labeling which does not conflict with the Federal Government's goals can be permitted.

For more information on these issues, please contact Robert M. Bodzin at 510.835.6833 or via e-mail at rbodzin@burnhambrown.com.

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[1]A more detailed analysis of the underlying case can be found in the author's December 12, 2002 Client Alert, which is available on www.burnhambrown.com.